

### REMARKS

Reconsideration of the above-identified patent application in view of the amendments and following remarks is respectfully requested.

Claims 66-70, 75, 76, 82 and 83 are under consideration in this application. Claims 1-65, 71-74 and 77-81 have been previously canceled. Claims 66-70, 75 and 76 stand rejected under 35 USC 103(a). Claims 66 and 67 are hereby amended. New claims 82 and 83 have been added.

### Background

The claims before the Examiner provide for securing a stent cover to a stent to make a stent assembly in a simple manner by providing a stent having bendable cover connectors disposed at the periphery of a stent end which are folded over a cover end, thereby secure the cover to the stent to form the stent assembly.

### History

The Application was filed December 29, 2003.

On July 7, 2005 the Applicant filed a preliminary amendment, cancelling claims 1-46 and presenting new claims 47 to 81.

On December 13, 2006 a restriction requirement was issued as the USPTO believed that claims 47-76 and claims 77-81 were distinct. On January 10, 2007, Applicant elected claims 47-76 for further examination.

On February 27, 2007 claims 66-73, 75 and 76 were rejected under 35 USC 102(b) as being anticipated by Bynon et al (US 5667523) while Claim 74 was identified as being allowable if rewritten in independent form.

In a Response received by the USPTO on May 29, 2007, the Applicant amended independent claim 66 to include the limitations of claim 74 and of all intervening claims in order to expedite prosecution while traversing all the rejections.

In an Office Action mailed September 19, 2007 the Examiner noted some typographical errors in the claims, which the Applicant subsequently amended in a Response received by the USPTO on October 25, 2007.

In an Office Action mailed January 23, 2008 the Examiner noted some typographical errors in the claims, which the Applicant later amended in a Response received by the USPTO on March 10, 2008.

In the Office Action sent July 9, 200, claims 66-70, 75 and 76 have been rejected as being unpatentable over Nolting (6,099,559) in view of King et al (5,192,311) under 35 USC 103(a).

#### **Amendments to the Claims**

Claim 66 has been amended by removing elements relating to the first ring-shaped wall section being a bent wire loop. Claim 66 currently includes only elements which were rejected on February 27, 2007 as being anticipated by Bynon et al (US 5667523).

New claim 82 dependent from claim 66 includes those elements removed from claim 66 by this amendment.

Claim 67 has been amended by removing elements that relate to the second ring-shaped wall section being a bent wire loop. Claim 67 currently includes only elements which were rejected on February 27, 2007 as being anticipated by Bynon et al (US 5667523) with reference to claim 67 and claim 71.

New claim 83 dependent from claim 67 includes those elements removed from claim 67 by this amendment.

#### **35 U.S.C. 102(b) Rejection – US 5,667,523 (Bynon et al)**

Original claim 66 as well as original claim 71 were rejected on February 27, 2007 under 35 USC 102(b) as being anticipated by Bynon et al (US 5667523). Applicant presumes that this rejection might be maintained.

*"To anticipate a claim, the reference must teach each and every claim element of the claims", MPEP 2131 and "In order to prove that a claim is anticipated under 35 USC 102(b), a single prior art reference must be shown to disclose each limitation of the claim" (in re Cruciferous Sprout Litig., 301 F.3d 1343, 1349-50 (Fed. Cir. 2002)).*

Bynon et al teaches an intraluminal graft sandwiched between two structural support layers, preferably a stent/graft/stent assembly (abstract).

Bynon et al does not teach at least one element of claim 66, that of *"a first ring-shaped wall section defining said first stent end, wherein part of an end thereof is one of said bendable cover connectors folded over said first cover end"*.

In the Office Action of February 27, 2007, column 12 lines 61-66 and Figure 11 of Bynon et al were relied on to reject claim 66 and claim 71 by identifying an end 64 or 66 of element 62 as a "cover connector" of the claim. Careful reading of column 12 lines 61-66 and study of Figure 11 of Bynon et al show that this is a mischaracterization of element 62.

In column 12 lines 61-66 and in Figure 11, Bynon et al teaches ends 64 and 66 of tubular graft 62 which are folded over the outside surface of stents 68 and 70. In contrast, in claim 66 the bendable cover connectors are part of an end of the first stent which are folded over an end of the stent cover.

Thus Bynon et al teaches ends of a graft folded over stents while claim 66 refers to bendable cover connectors which are part of a stent folded over a stent cover.

In conclusion, Bynon et al cannot anticipate claim 66 because Bynon et al does not teach all the elements of claim 66 (MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999)). Since Bynon et al does not teach all elements of claim 66, claim 66 and claims 67-70, 75, 76, 82 and 83 dependent therefrom are not anticipated by Bynon et al.

**35 U.S.C. 103 Rejections – US 6,099,559 (Nolting) in view of US 5,192,311 (King et al)**

The previously presented claims 66-70, 75 and 76 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,099,559 (Nolting) in view of US 5,192,311 (King et al). Applicant respectfully traverses this rejection.

In order to establish a *prima facie* case of obviousness, all claim limitations must be taught or suggested by the prior art (MPEP 2143.03, in re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974))

Neither Nolting nor King et al teach at least one element of the claims, that of *"a first ring-shaped wall section defining said first stent end, wherein part of an end thereof is one of said bendable cover connectors folded over said first cover end"*.

Nolting teaches a stent assembly including a tubular stent cover 22 covering the outside surface of a first stent 12 made of a plurality of joined-together tubular stent sections 14 (column

3 lines 57-65). Second and third stents **18** and **19** encircle the ends of first stent **12** and stent cover **22** so that stent cover **22** is sandwiched between first stent **12** and stents **18** and **19**. Stents **18** and **19** are joined to first stent **12** at one or more adjacent stent sections (column 4 lines 11-12) by fusing, welding, soldering or other suitable manner (column 4 lines 42- 47).

Thus Nolting teaches cover connectors (stents **18** and **19**) that encircle the ends of stent **12** and stent cover **22**. Nolting does not teach cover connectors which are part of an end of a *ring-shaped wall section defining an end of the first stent* and does not teach cover connectors that are "*folded over said first cover end*".

The relevance of King et al is to the claimed invention is unclear as King et al does not relate to stents or stent assemblies. Even when, for the sake of argument, one stretches structural equivalences far beyond what could be reasonably understood by a person having ordinary skill in the art, King et al does not teach the elements of the claims that are missing from Nolting.

King et al. relates to a tube (e.g., of polyurethane) called a substrate **22** on which an autologous graft is grown, *in vivo*. Substrate **22** is tethered inside a blood vessel of a subject to allow blood flow through the lumen and along the outer surface of the substrate **22** (Figure 8). A graft gradually grows on surfaces of substrate **22** and when complete, substrate **22** is removed from the body of the subject and the graft separated from substrate **22**.

In some embodiments it is desired to strengthen the produced graft so a floppy mesh tube **53** (column 9 starting line 5) or **61** (column 10 line 20) of woven filaments, e.g., Dacron or monofilament nylon (column 9 lines 26 - 30) is secured to and supported by (column 9 line 6, column 10 line 40, column 11 line 16) substrate **22**. In some embodiments, parts of mesh tube **53** or **61** are folded over the ends of substrate **22** (Figure 5).

Seemingly, in the Office Action floppy mesh tube **53** or **61** has been mischaracterized as an "*expandable tubular stent body*" of claim 66. Mesh tube **53** or **61** is not "expandable" so cannot be read as the "*expandable tubular stent body*" of claim 66. Mesh tube **53** or **61** is not a "stent" so cannot be read as the "*expandable tubular stent body*" of claim 66. A floppy woven mesh tube **53** or **61** that must be supported by substrate **22** and which function is to be coated with collagenous growth cannot be considered a stent which is an object "*suitable for maintaining the patency of a bodily lumen*" (abstract of the specification of the instant patent application).

"All words in a claim must be considered in judging the patentability of that claim against the prior art (in re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)). Claim 66 includes the element that the expandable tubular stent body comprises "*bendable cover connectors*". Applicant notes that the word "bendable" is not used in the English language to describe floppy tubes such as woven mesh tube 53 or 61: socks, for example, are not "bendable". Since no part of woven mesh tubes 53 and 61 is bendable and claim 66 requires that the cover connectors of the tubular stent body be bendable, floppy mesh tube 53 or 61 cannot be considered a "*tubular stent body*".

In conclusion, a *prima facie* case of obviousness has not been made as claim 66 and therefore claims 67-70, 75, 76, 82 and 83 dependent therefrom (in re Fine, 837 F.2d 1071, 5USPQ2d 1596 (Fed. Cir. 1988)) cannot be considered as being unpatentable over Nolting and King et al because the combined references do not teach or suggest all claim elements.

Independent claim 66 defines a stent assembly that is neither anticipated by nor obvious in light of the art. Applicant is of the opinion that independent Claim 66, and consequently all claims dependent therefrom, are in condition for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

If it would advance the prosecution of this application, the Examiner is invited to contact applicant's representative at the below indicated telephone number.

Respectfully submitted,



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